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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/717,450 | 11/20/2000 | Lisa Ann Neuhold | 0630/D532US1 | 5417 |

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| EXAMINER |
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WILSON, MICHAEL C

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| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/717,450

Applicant(s)

NEUHOLD ET AL.

Examiner

Michael C. Wilson

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

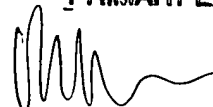
Claim(s) objected to: _____.

Claim(s) rejected: 55-96.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

MICHAEL WILSON
PRIMARY EXAMINER



Continuation of 2. NOTE: The limitation of "joint-specific promoter" would require considerations under enablement and written description not previously required. While the phrase "joint-specific promoter" is used throughout the specification, the only promoter described in the specification or in the art at the time of filing that was specific to the joint was type II collagen promoter (pg 6, line 15-17). If other "joint-specific promoters" were known in the art at the time of filing, please provide support. Claims 90-96 as proposed would require an indefiniteness rejection because it is unclear whether "which degradation..." in the preamble is an active step of degrading collagen or a phrase used to describe structure of the transgenic mammal that is given the compound - especially because the transgenic mammal may not yet have degradation of Type II collagen. The proposed changes in claims 90-96 make the claims confusing and do not clearly set forth the active steps of the methods or the products used in the methods.

Continuation of 5. does NOT place the application in condition for allowance because: While the phrase "joint-specific promoter" is used throughout the specification, the only promoter described in the specification or in the art at the time of filing that was specific to the joint was type II collagen promoter (pg 6, line 15-17).

Applicants argue Nieman (1998, Transgenic Res., Vol. 7, pg 73-75) has been misinterpreted by the examiner. Applicants argument is not persuasive. Nieman is relied upon as teaching different promoters have different effects on the resulting phenotype of transgenics. Joint-specific promoters are required to obtain the phenotype claimed; however, Applicants have not provide any promoters that provide joint specificity other than the type II collagen promoter.

Applicants arguments regarding the breadth of non-human mammal have been considered but are not persuasive for reasons of record. Applicants arguments regarding the indefiniteness rejections are moot because the proposed amendment was not entered.

Claims 55-96 remain rejected for reasons of record under written description, enablement, and indefiniteness.